

REMARKS

Claims 25-32 and 34-38 are pending. Claims 25 and 34 are newly amended. Claims 39-41 are newly added. The amendments find support in the claims as originally filed and in the specification. No new matter is added.

Specifically, support for the amendment to claim 25 which requires that the brush be attached to the inner tube of the collection device, can be found throughout the specification as published in document number 20050020937A1 by the USPTO, including paragraph 0020, as follows:

“As shown in FIGS. 1A and 1B, the device comprises a brush attached to an inner tube, and an outer tube that serves as shield to the brush and the inner tube. The brush includes a longitudinal axis that runs through the inner tube and bristles that extend laterally outward from the longitudinal axis. The brush and the inner tube as a whole are called the collection element. The inner and outer tubes are preferably cylindrical in shape, and are approximately equal length. The collection element can be removed from the shield for sample analysis. Alternatively, the bristles can have short axis that is mounted to the base of the inner tube, and the bristles can be removed from the base of inner tube”, paragraph 0020 of the published application”.

Drawings

The office action indicates that that new corrected drawings in compliance with 37 C.F.R. 1.121(d) are required in this application. Accordingly, Applicant has submitted herein a new set of drawings. Applicant notes that the drawings are not color photographs, nor are they copies of color photographs.

Claim Objections and Rejections

The Office Action states that claim 25 is objected to because of the following informality: the positive recitation in line 1 of “for detecting the presence” should apparently read “for detecting a presence”. Applicant respectfully traverses on the grounds that the term “the” in the phrase “the presence” is acting as a descriptive element, not being used as a means for positively

setting forth each element or component. MPEP 2173.05(e) states that a claim is indefinite when it contains words or phrases whose meaning is unclear. Applicant contends that the phrase “the presence” is not indefinite because the claim at issue apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, paragraph 2.

The Office Action states that claim 27 is objected to because of the following informality: the positive recitation in line 2 of “the form” should apparently read “a form”. Applicant respectfully traverses on the grounds that the term “a” in the phrase “a form” is acting as a descriptive element, describing the inherent feature of the claimed device. The claim at issue apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, paragraph 2.

The Office Action states that claim 36 is objected to because of the following informality: the positive recitation in line 2 of “the length” should apparently read “a length”. Applicant respectfully traverses on the grounds that the term “the” in the phrase “the length” is acting as a descriptive element, describing the inherent feature of the claimed device. Changing this to “a length” would render the claim indefinite.

The failure to provide explicit antecedent basis for terms does not always render a claim indefinite, MPEP 2173.05(e).

Specifically MPEP 2173.05(e) states:

“Inherent components of elements recited have antecedent basis in the recitation of the components themselves. For example, the limitation “the outer surface of said sphere” would not require an antecedent recitation that the sphere has an outer surface. See *Bose Corp. v. JBL, Inc.*, 274 F.3d 1354, 1359, 61 USPQ2d 1216, 1218-19 (Fed. Cir 2001)”.

Thus, the claim at issue apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, paragraph 2.

The Office Action states that claim 37 is objected to because of the following informality: the positive recitation in line 2 of “the group” should apparently read “a group”. Applicant respectfully traverses on the grounds that the phrase “the group” is part of a larger phrase containing the Markush language of “selected from the group consisting of...”

Specifically MPEP 2173.05(h) discloses:

“One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C." See Ex parte Markush, 1925 C.D. 126 (Comm'r Pat. 1925)”.

In light of the teachings of MPEP 2173.05(h), Applicant respectfully contends that the outstanding objection is misapplied to the instant claim.

In light of the above amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of these objections.

Claim Rejections – 35 USC § 112, second paragraph

Claim 34 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The office action indicates that claim 34 provides for the use of a method for detecting high risk HPV, but since the claim does not set forth any steps involved in the method/process, it is unclear what method/process Applicant is intending to encompass. Applicant notes that claim 34 is dependent from claim 25 which has the method steps for detecting *any* HPV. However, Applicant has newly amended claim 34 by adding the limitation “wherein detection of the presence of high risk HPV comprises assaying the specimen for the presence of high risk HPV”.

In light of the above amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the rejection.

Claim Rejections – 35 USC § 101

Claim 34 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps in the process, results in an improper definition of a process. Applicant notes that claim 34 is dependent from claim 25 which has the method steps for detecting *any* HPV. Claim 34 only further limits the subtypes of HPV detected in the method of claim 25 from which it depends. However, as described above, Applicant has newly amended claim 34 by adding the limitation “wherein detection of the presence of high risk HPV comprises assaying the specimen for the presence of high risk HPV”.

In light of the above amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the rejection.

Claim Rejections – 35 USC § 102

Claims 25-27 and 34-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Edens et al. (6,521,190 B1)

Applicant respectfully traverses. Anticipation requires that the purported prior art reference disclose each and every limitation of the claims. *Atlas Powder Company et al. v. IRECO, Incorporated et al.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999). Applicant contends that Edens et al. does not teach each and every limitation of the instant claims as newly amended.

Edens et al. teach:

“A collection apparatus comprising a collection container comprising a first interior portion, second interior portion and third interior portion, wherein the first interior portion of the container extends from an open end to the second interior portion and defines a first central axis; the second interior portion extends inwardly and has a decreasing cross-sectional area from the first interior portion to the third interior portion, and defines a second central axis at an oblique angle with respect to the first central axis, the second interior portion being sized to engage bristles of a brush device having a body of bristles on a shaft and to urge the shaft of the brush device at an angle with respect to the first central axis; the third interior portion extends from the second interior portion and defines a closed end;

and the first, second and third interior portions are sized and arranged to form an unencumbered straight line path from the open end to the closed end of the collection container”, claim 1. Also see Figure 2.

Note that the method of Eden et al. uses a cervical brush which can fit into the collection device and must be completely removed from the collection device when the sample cells are being collected. Accordingly, in the methods taught by Eden et al., the sample is collected with a brush, and subsequent to sample collection, the brush containing the sample is then positioned (and stored) in Eden’s claimed collection chamber with cytology fluid at the bottom of the chamber in such a way that a pipette tip can later access the fluid surrounding the brush without being impeded by the presence of the brush. The brush must be a separate device

In contrast, the instant claims, as newly amended, require that the brush used for sample collection ***be attached*** to the retractable inner tube of the device. This unitary structure has the net effect that the entire device is used during sample collection. (See Figures 1A and 1B, and paragraphs 20 and 22 of the published application). As depicted in the specification:

“As shown in FIGS. 1A and 1B, the device comprises a brush attached to an inner tube, and an outer tube that serves as shield to the brush and the inner tube. The brush includes a longitudinal axis that runs through the inner tube and bristles that extend laterally outward from the longitudinal axis. The brush and the inner tube as a whole are called the collection element”, paragraph 0020 of the published application, and

“In the self-sampling method described herein, one preferred embodiment comprises inserting the collection device into the vagina, protruding the collection element out to have the bristles contact with the cervical/vaginal tissues, rotating the inner tube of the collection element, withdrawing the collection element back into the shield, and taking the whole collection device out of the body. The bristles containing the vaginal sample is then immersed into a liquid collection medium”, paragraph 0022 of the published application.

Thus, the device used in the method of Eden et al. and the device used in the present method are entirely different. Because the instantly claimed methods for detecting the presence of a human papilloma virus require the use of a device that is structurally distinct from the device used in the methods taught by Eden et al., the teachings of Eden et al are not anticipatory.

This distinction in the structural design of the device encompassed by the instant claims has the added advantage of allowing self collection because Applicant's device does not require precise location of the collection element inside the cervical/vaginal tract to collect cervical cells. Thus, Applicant's device makes the procedure easy to operate by the patient having no training in collecting cervical/vaginal specimen, as disclosed in the instant specification.

In view of the claim amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the instant rejection.

Claims Rejections – 35 USC § 103

Claims 28-32 are rejected under are obvious over Edens, in view of Zavada (US2003/0049828).

Applicants respectfully traverse on the grounds that neither Edens alone, nor when combined with Zavada, teach all the limitations of the instant claims as newly amended. Applicants submit that for a determination of obviousness to be proper, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974).

As discussed in the rebuttal to the 102 rejection, Edens et al. does not teach a method for detecting HPV in a vaginal specimen comprising the use of a specimen collection device where a brush is attached to the collection device, as required by the newly amended claims.

Zavada et al.'s teaching of methods comprising assaying bodily fluids for the presence of MN proteins using antibodies and proteins does not make up for Eden et al.'s not teaching a unitary device as required by the instant claims.

Therefore, Applicants contend that the teachings of Eden et al., either alone or in combination with Zavada et al., do not teach all the limitations of the claims as newly amended.

In view of these distinctions of the instant invention from both the references cited in the Office Action and the references disclosed in the background section of the instant specification, Applicants contend the instant newly added claims are not anticipated or made obvious by these references.

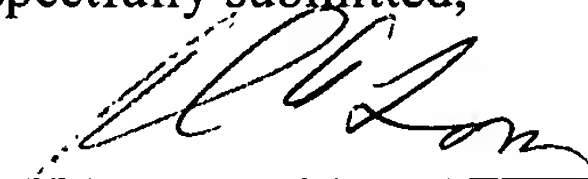
Conclusion

Applicant submits that all claims are allowable as written and respectfully request early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicant's attorney/agent would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney/agent of record.

Date:

13 June 2008

Respectfully submitted,



Name: Ralph Loren

Registration No.: 29,325

Customer No.: 21874

Edwards Angell Palmer & Dodge LLP

111 Huntington Avenue

Boston, MA 02199-7613

Tel. (617) 239-0100